This Page Is Inserted by IFW Operations
and is not a part of the Official Record

# BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

# IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.**

**PCT** WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

# INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|---|---|---|
| **(51) International Patent Classification ⁵ :**<br>A61M 29/02, 25/01 | A1 | **(11) International Publication Number:** WO 92/00775<br>**(43) International Publication Date:** 23 January 1992 (23.01.92) |

**(21) International Application Number:** PCT/US91/04753

**(22) International Filing Date:** 3 July 1991 (03.07.91)

**(30) Priority data:**
547,665 3 July 1990 (03.07.90) US

**(71) Applicant:** MALLINCKRODT MEDICAL, INC. [US/US]; 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134 (US).

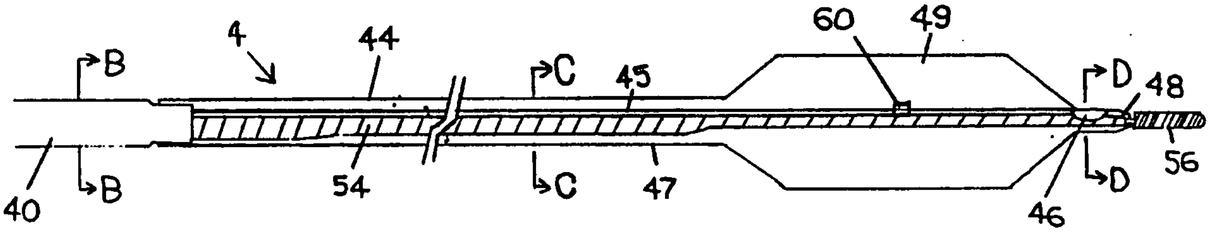
**(72) Inventors:** JENDERSEE, Bradly, A. ; 2131 Masters Lane, Missouri City, TX 77459 (US). SOLANO, Scott, J. ; 55 South Calla Lily Court, Lake Jackson, TX 77566 (US).

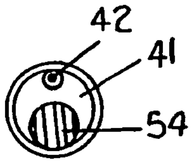
**(74) Agents:** HEY, David, A. et al.; Mallinckrodt Medical, Inc., 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134 (US).

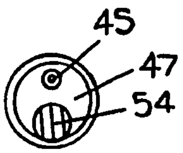
**(81) Designated States:** AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

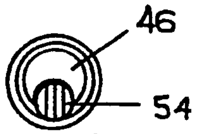
**Published**
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

**(54) Title:** PTCA CATHETER HAVING AN OPTIONALLY FIXATED COREWIRE









**(57) Abstract**

The present invention relates to a percutaneous transluminal coronary angioplasty (PTCA) catheter (4) having an optionally fixated corewire (54). In particular the present invention relates to a PTCA catheter which may be optionally used as an over the wire catheter, a fixed wire catheter, or a semi-movable catheter, and which may be infinitely switched between the different types of catheters at any time during an angioplasty procedure.

### *FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | |
|---|---|
| AT | Austria |
| AU | Australia |
| BB | Barbados |
| BE | Belgium |
| BF | Burkina Faso |
| BG | Bulgaria |
| BJ | Benin |
| BR | Brazil |
| CA | Canada |
| CF | Central African Republic |
| CG | Congo |
| CH | Switzerland |
| CI | Côte d'Ivoire |
| CM | Cameroon |
| CS | Czechoslovakia |
| DE | Germany |
| DK | Denmark |
| ES | Spain |
| FI | Finland |
| FR | France |
| GA | Gabon |
| GB | United Kingdom |
| GN | Guinea |
| GR | Greece |
| HU | Hungary |
| IT | Italy |
| JP | Japan |
| KP | Democratic People's Republic of Korea |
| KR | Republic of Korea |
| LI | Liechtenstein |
| LK | Sri Lanka |
| LU | Luxembourg |
| MC | Monaco |
| MG | Madagascar |
| ML | Mali |
| MN | Mongolia |
| MR | Mauritania |
| MW | Malawi |
| NL | Netherlands |
| NO | Norway |
| PL | Poland |
| RO | Romania |
| SD | Sudan |
| SE | Sweden |
| SN | Senegal |
| SU | Soviet Union |
| TD | Chad |
| TG | Togo |
| US | United States of America |

# PTCA CATHETER HAVING AN OPTIONALLY FIXATED COREWIRE

## Background of the Invention

The present invention relates to low profile percutaneous transluminal coronary angioplasty (PTCA) catheters. In particular, the present invention relates to PTCA catheters which allows for optional fixation of a corewire for the catheter.

PTCA procedures typically are performed using a guiding catheter which may be percutaneously introduced into the cardiovascular system of the patient through the brachial or femoral arteries and advanced therein until the tip thereof is in the ostium of the desired coronary artery. A guidewire and a dilatation balloon catheter are then introduced through the guiding catheter, the guidewire being disposed within an inner lumen of the balloon catheter. The guidewire and balloon are advanced until the dilatation balloon is properly located within the area of lesion to be treated. Once positioned, the dilatation balloon in inflated to a predetermined size using a radiopaque liquid, such as contrast medium, in order to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The dilatation balloon is then deflated and the balloon catheter removed so that blood flow may be resumed through the dilated artery.

Prior art PTCA catheters have typically employed one of three basic designs: over the wire (OTW), fixed wire (FW) or semi-movable wire (SMW), each of which has its own distinct advantages and disadvantages. The user of such prior art catheters has been forced to accept the disadvantages associated with the chosen design in order to gain the particular advantages provided by the chosen design.

Over the wire (OTW) catheters are the oldest type of PTCA catheter available. FIG. 1A shows a typical design for an OTW catheter, generally designated by reference numeral 1, which employs a two lumen shaft, the two lumens being either coaxially disposed (FIG. 1B) or provided in a multi-lumen configuration (FIG. 1C). A first lumen 12, passes through the entire length of the catheter 1, and accepts an independently manipulated guidewire 10. A second lumen 14, communicates with the inside of a dilatation balloon 16, and constitutes a passageway for injection of contrast medium into the balloon 16 for inflation thereof. In operation of the OTW catheter 1, the guidewire 10, is first passed through the artery to be treated to the area of lesion, and then is passed on through the area of lesion. The catheter 1, is then advanced over the guidewire 10, by slidingly engaging the first lumen 12, over the guidewire 10, until the balloon 16, is properly located within the area of lesion. The balloon 16, is then inflated using contrast media supplied through lumen 14, to radially compress the atherosclerotic plaque in the lesion area against the artery wall. Following dilation of the artery, the catheter 1, and guidewire 10, may be removed. Alternatively, the catheter 1, alone may be removed while leaving the guidewire 10, in place, thus maintaining access to the artery for other devices that may be required.

Advantages of OTW catheters include the ability to remove the catheter while leaving the guidewire in place, thus providing access to the artery for other devices without loss of position within the area of lesion, as noted above. This also provides a relatively high margin of safety, because maintaining access to the artery is crucial should the lesion abruptly reclose following dilation, an occurrence which takes place in about six percent (6%) of all cases. In addition, the OTW catheter has the advantage of allowing the user to choose specific guidewires and catheters independently thereby allowing the user to determine the optimal combination for each case.

A main disadvantage of the OTW catheter is the relatively large profile needed to house the two discrete lumens. This is particularly a problem when it is necessary to cross a tight lesion. Further, the OTW catheter requires relatively complex operation because of the necessity of manipulating two independent elements of the catheter; i.e. the guidewire and the balloon catheter.

FIGs. 2A and 2B show a typical fixed wire (FW) catheter, generally designated by reference numeral 2, which utilizes a single lumen shaft 20, which communicates directly with the proximal end of a balloon 22, and is sealed at a distal end 24, located distally to the balloon. A tapered corewire 26, similar to that inside a conventional guidewire, runs the entire length of the catheter 2, inside the single lumen, and extends beyond the distal end 24, of the catheter 2, terminating in a conventional guidewire tip 28. The shaft 20, is sealed directly to the core wire 26, at the distal end 24, by suitable sealing means. In operation, the FW catheter 2, sealed to the core wire 26, is guided as a single unit, through the artery to be treated, by manipulating the entire device like a guidewire until the balloon 22, is properly positioned within the area of lesion. Dilatation is then carried out by supplying contrast medium through the single lumen to inflate the balloon 22. Following dilatation, the entire device, i.e. the catheter 2, with sealed core wire 26, is removed.

A major advantage of an FW catheter, is the relatively small profile enabled by the utilization of a single lumen in the catheter shaft, with no lumen present in the area under the balloon. The deflated balloon profile for an FW catheter is consequently considerably smaller than the deflated balloon profile for an OTW catheter. In addition, the shaft diameter of an FW catheter is smaller, which allows for easier and better injections of contrast medium through the guiding catheter and around the shaft of the FW catheter. Also, an FW catheter has the advantage of being relatively easy to use. Because all elements of an FW catheter are fused together, it operates as a single element and may be manipulated easily by a single operator, thus making the dilatation procedure simpler and faster. Another advantage of an FW catheter relates to the pushibility of the catheter. Because the core wire is firmly attached to the distal end of the shaft, the operator can transmit a large amount of longitudinal force to the catheter, aiding in pushing the device across lesions in tortuous areas.

A major disadvantage of an FW catheter is the loss of position within the artery upon removal of the catheter following dilatation. Because an FW catheter acts as a single element, the entire catheter must be removed following dilatation, resulting in a loss of easy access to the artery being treated. Therefore, if it is necessary to insert a further device into the lesion area of the artery, a second wire or catheter must be inserted to recross the lesion, which increases the difficulty and risks of the procedure. A second disadvantage of an FW catheter is a compromise in the steerability of the tip of the catheter. Although the corewire is essentially like a guidewire, the distal end of the catheter shaft is fixed near the end of the corewire, with the result that the balloon tends to act as an anchor on the core wire and thus reduces steerability and performance.

A semi-moveable wire (SMW) catheter is shown if FIG. 3 and represents a compromise between an OTW catheter and an FW catheter. In particular, an SMW catheter, generally designated by reference numeral 3, utilizes a coaxial two lumen design similar to that of an OTW catheter as shown in FIG. 1B, so that a guidewire 34, can move freely within a first lumen 30. A second lumen 38, is provided as means for injecting contrast medium into a balloon 32. The first lumen 30, and second lumen 38, are fused together at their distal ends. In order to decrease profile, the portion of the first lumen 30, under the balloon 32, is tapered to a much smaller size than the portion of the first lumen 30, in the proximal portion of the catheter 3. The guidewire 34, is also tapered so as to fit into the taper of the first lumen 30, while maintaining free rotation and allowing advancement to a small extent (usually about 12 cm). A standard guidewire tip 36, is attached to the end of the guidewire 34. An SMW catheter is operated in much the same manner as an FW catheter. However, because the guidewire 34, may freely rotate and be advanced independently of the catheter shaft, steering of the guidewire 34, across a lesion may be accomplished without the balloon 32, and shaft acting as an anchor. Upon completion of dilatation, the entire FW catheter, including the guidewire 34, must be removed. This is because the tapered portion of the first lumen 30, is smaller in diameter than the guidewire 34, in the proximal end of the catheter 3, as well as being smaller in diameter than the guidewire tip 36. Therefore, the tapered portion of the inner lumen 30, is bracketed by larger portions of the guidewire 34, and simultaneous removal of both the catheter 3, and guidewire 34, is necessitated.

Advantages of an SMW catheter include a smaller profile and greater simplicity of use as compared to conventional OTW catheters. Also, an SMW catheter has the advantage of better wire movement, i.e. steerability, as compared to an FW catheter.

An SMW catheter has the same disadvantages as an FW catheter as related to maintaining access to the lesion area following dilatation. Further, an SMW catheter has a disadvantage of having a larger profile as compared to FW catheters.

## Objects of the Present Invention

It is an object of the present invention to provide a single catheter that can be used as an OTW catheter, an FW catheter, and an SMW catheter.

It is a further object of the present invention to provide a catheter that can be operated as any of an OTW, FW, or SMW catheter and which allows the operator to change from one to the other at any time during an angioplasty procedure.

It is a further object of the present invention to provide a catheter that contains an optionally inflatable seal at its distal end, for the purpose of selectively fixing a corewire within the tip of the catheter.

It is a further object of the present invention to provide a catheter that contains an optionally inflatable seal at its distal end, for the purpose of purging air from the catheter prior to use.

## Summary of the Invention

The objects of the present invention are accomplished by providing a PTCA catheter comprising a multi-lumen shaft having a first large main lumen through which a corewire may be provided and through which contrast medium may be supplied in order to inflate a balloon attached near the distal end of the catheter shaft. The multi-lumen shaft also includes a second small lumen which travels the entire length of the catheter, terminating at a small balloon which acts as an inflatable seal, disposed within the distal tip of the catheter shaft. By inflating the inflatable seal, a corewire passing through the first lumen may be locked in place so that the catheter acts as an FW catheter. Once inflated, the inflatable seal also seals the distal end of the catheter, allowing the dilatation balloon to be inflated. When the inflatable seal is in a deflated condition, free rotation and longitudinal movement of the corewire is enabled so that the catheter acts as an SMW catheter. Moreover, relative sizes of the corewire and first lumen are such that the catheter shaft may be entirely removed from the corewire while leaving the corewire in place within the artery being treated, thus providing all of the advantages of an OTW catheter. The inflatable seal in the tip of the catheter according to the present invention, may be inflated and deflated repeatedly and at any time during a dilatation procedure in order to give the operator the option of using the optimal type of device (i.e. OTW, FW or SMW catheter) at different stages of the procedure.

## Brief Description of the Drawings

FIG. 1A is a plan view of a typical OTW catheter as known in the prior art.

FIG. 1B is a cut away end view of an OTW catheter shaft having coaxially disposed lumens as known in the prior art.

FIG. 1C is a cut away end view of an OTW catheter shaft having a multi-lumen configuration as known in the prior art.

FIG. 2A is a plan view of a typical FW catheter as known in the prior art.

FIG. 2B is a expanded view of the distal portion of the FW catheter shown in FIG. 2A.

FIG. 3 is a plan view of a typical SMW catheter as known in the prior art.

FIG. 4A is a plan view of a catheter according to the present invention.

FIG. 4B is a cross-sectional end view of the catheter shaft according to the present invention taken along line B-B of FIG. 4A.

FIG. 4C is a cross-sectional end view of the catheter shaft according to the present invention taken along line C-C of FIG. 4A.

FIG. 4D is a cross-sectional end view of the catheter shaft according to the present invention taken along line D-D of FIG. 4A.

FIG. 4E is an expanded view of the proximal end of the catheter according to the present invention.

## Detailed Description of the Present Invention

FIG. 4A is a plan view of a catheter, generally designated by reference numeral 4, according to the present invention. In particular, the catheter 4, includes a multi-lumen proximal shaft 40, having a large main lumen 41, and a very small secondary lumen 42. (See FIG. 4B). The proximal shaft 40, is bonded to a balloon extension 44, proximal to a dilatation balloon 49. The main lumen 41, communicates directly with the interior of an outer member 47, of the balloon extension 44, while the secondary lumen 42, is bonded to a small inner member 45, of the balloon extension 44. (See FIG. 4C). The inner member 45, extends the entire length of the balloon extension 44, and terminates at a small inflatable seal 46, disposed within a distal tip 48, of the catheter 4. (See FIG. 4D). The outer member 47, also extends the entire length of the balloon extension 44, including a section making up the dilatation balloon 49, and ultimately opens at the distal tip 48, of the catheter 4. A single radiopaque marker band 60, is positioned on the inner member 45, to fluoroscopically delineate the center of the dilatation balloon 49.

The catheter 4, terminates at its proximal end in a standard adjustable Y connector, generally designated by reference numeral 50, as shown in FIG. 4E. The main lumen 41, continues through the length of the connector 50, and terminates at a gasket 52. The gasket 52, allows a corewire 54, to pass therethrough while providing a seal around the corewire 54, which prevents fluid from leaking out the proximal end of the catheter 4. The corewire 54, passes through the entire length of the main lumen 41, and the outer member 47, and emerges from the opening in the distal tip 48, of the catheter 4. The connector 50, includes a first inflation leg 53, communicating with the secondary lumen 42, and allowing for independent inflation of the inflatable seal 46. The connector 50, further includes a second inflation leg 58, communicating with the main lumen 41, and allowing for inflation of the dilatation balloon 49.

Preferably, all of the components of the catheter 4, are composed of oriented polyethylene so that the components may be heat bonded together, thus simplifying manufacturing carried out using well known processes. The proximal shaft 40, may be formed of a high density polyethylene material, which provides a relatively stiff shaft having increased pushibility and a low friction coefficient for better corewire movement. The inner member 45, and the outer member 47, of the balloon extension 44, may be formed of a linear low density polyethylene to provide flexibility and strength. The outer member 47, may also be formed of other materials that provide various combinations of pushibility and flexibility, such as, PET, Nylon, Nylon blends, stainless steel, polyimide, etc. The inner member 45, is preferably formed of oriented linear low density polyethylene, so that it may be heat bonded to the other components of the catheter. Other materials could be used as well, including PET, Nylon, Nylon blends, polyimide, or elastomeric materials such as silicone or latex.

The inflatable seal 46, is preferably formed as an integral portion of the inner member 45, by heating the end portion or the inner member 45, while expanding the end portion under pressure. The dilatation balloon 49, may be formed as an integral portion of the outer member 47, in the same manner. By forming the balloons as integral portions of the members, the need for separately bonding balloons onto the members is obviated. The inflatable seal 46, may be heat bonded to the interior surface of the outer member 47, by deflating the inflatable seal 46, and inserting a mandrel inside the lumen of the inner member 45, to provide support. The integrities of the inflatable seal 46, and dilatation balloon 48, can be maintained by controlling the application of heat during formation. The inflatable seal 46, may also be made of an elastomeric material, such as silicone, latex rubber, or polyurethane and adhesively bonded to the inner member 45, and distal tip 48.

The proximal end of the balloon extension 44, is preferably heat bonded to the distal end of the proximal shaft 40, in a well known manner. Further, the proximal shaft 40, and balloon extension 44, are preferably bonded at a position 5 to 35 cm proximal to the dilatation balloon 49. The outer diameter of the main lumen 41, and outer member 47, are approximately the same in order to assure a smooth transition and strong bond therebetween. Also, the inner diameter of the secondary lumen 42, and the inner member 45, are approximately the same to assure a smooth transition and strong bond therebetween. The diameter of the main lumen 41, and outer member 47, is preferably in the range of 3 to 6 times greater than the diameter of the secondary lumen 42, and inner member 45. The relatively small diameter of the secondary lumen 42, and inner member 45, allows the catheter 4, to approximate the overall dimensions of a single lumen catheter, thus reducing the profile to that of a FW catheter, while maintaining the advantages of an OTW catheter.

The corewire 54, is preferably of a tapered configuration, tailored to provide the optimal combination of flexibility and pushibility. The diameter of the proximal untapered portion of the corewire 54, is preferably in a range from .010" to .020". The taper preferably begins about 15 to 35 cm from the distal tip of the corewire 54, and includes at least two discrete tapers separated by a length of untapered core. Most preferably, the portion of the corewire 54, which will be in place within the dilatation balloon 49, has a diameter of about .006" and then quickly tapers toward the distal end of the corewire 54, ending in a coil of radiopaque metal 56. The small diameter of the corewire 54, under the dilatation balloon 49, helps to minimize the profile of the deflated dilatation balloon 49. The corewire 54, may be formed of any suitable material, but is preferably formed of stainless steel or an alloy of nickel and titanium (nitinol).

It is also preferable to coat the surface of the corewire 54, with a lubricous material, such as, Teflon, silicone, hydrogel or other substances, in order to reduce friction between the corewire 54, and the outer member 47. In addition, the outer surface of the catheter 4, may be coated with a similar lubricous substance, such as silicone or hydrogel, in order to reduce friction of the outer surface of the catheter 4, during use.

The catheter according to the present invention may operate as any one of an OTW, FW, or SMW catheter at the option of the physician. Further, the physician may select the type of catheter he would like to use, at any time during the angioplasty procedure. This selectivity is enabled by the inclusion of the inflatable seal in the distal tip of the catheter. Further advantages of the catheter according to the present invention, include the ability to rapidly purge air from the catheter, and the relatively low profile of th catheter shaft and dilatation balloon made possible by the elimination of a large inflation lumen.

The overall design of the catheter according to the present invention is similar to an FW catheter, in that a single lumen is utilized for both inflation/deflation of the dilatation balloon and for passage of the corewire. This single lumen design assures a small profile for the catheter shaft and dilatation balloon. However, the catheter according to the present invention can also act as an SMW catheter, because the inflatable seal in the distal tip of the catheter allows the corewire to move freely within the main lumen. In other words, unlike a standard FW catheter, the corewire in the catheter according to the present invention does not have to be sealed at the distal tip of the catheter, thereby allowing the free movement of the corewire. Upon inflation of the inflatable seal the corewire is locked into place so that the catheter may operate as an FW catheter. Further, inflation of the inflatable seal seals the distal tip of the catheter, so that inflation and deflation of the dilatation balloon may be carried out through the main lumen. In addition, the catheter according to the present invention provides all of the advantages of an OTW catheter. In particular, if a corewire is already in place within the patient, the corewire supplied with the present catheter may be removed, and then the catheter shaft may be introduced to the patient over the corewire already in place. Also, if it is desired to introduce further devices following dilatation using the present catheter, the catheter shaft may be removed while leaving the corewire in place, thus maintaining access to the treatment area.

One method of using the catheter according to the present invention is described below.

As with all balloon catheters, air within the catheter must be purged from the catheter shaft and dilatation balloon prior to introduction of the catheter into the patient. This purging in necessitated by the need for an air-free hydraulic system to enhance inflation pressure, and also by the need to protect against injection of air into the coronary artery should the balloon rupture during the angioplasty procedure. In the catheter according to the present invention, this purging may be performed very easily and quickly, thus providing one advantage of the present invention. By drawing a vacuum on the inflatable seal the distal tip of the main lumen is entirely open, so that purging of air may be easily accomplished by injecting contrast medium through the main lumen from the proximal end and out the distal tip, until all air is seen to exit from the distal tip. This purging may be accomplished very rapidly when compared to prior art catheters because the distal tip opening of the catheter according to the present invention is much larger than the small pores or opening provided for purging purposes in the prior art catheters.

The catheter according to the present invention will normally be packaged with the corewire already installed through the main lumen. However, if the physician already has a corewire in place within the patient, the corewire may be removed and the catheter may be used as an OTW catheter. In other words, the catheter may be introduced to the patient over the corewire already in place. Once introduced, the catheter may be locked into place over the existing corewire, at any time, by simply inflating the inflatable seal in the distal tip of the catheter. Therefore, the enhanced pushibility of an FW catheter may by attained. In any case, once the balloon is properly located within the area of treatment, the inflatable seal is inflated to seal the distal end of the catheter, and inflation/ deflation of the dilatation balloon may be carried out by injecting contrast medium through the main lumen and into the dilatation balloon. Once an initial dilation has been carried out, the physician continues to have several options. In particular, if it desired to introduce a further device to the treatment area, the catheter may be removed while leaving the corewire in place. Further, the catheter may be used as any of an OTW, FW, or SMW catheter to access and dilate other lesions as the physician feels appropriate.

In one alternative, if the physician initially prefers an FW catheter, the inflatable seal may be inflated immediately following purging, in order to lock the corewire in place. The corewire and catheter may then be guided to the area of treatment within the artery as a single unit. When the dilatation balloon has been properly located within the lesion, the dilatation balloon may be immediately inflated as described above. Following this initial dilation, the physician has the same options as described above, (i.e. leave the corewire in place or continue to use the catheter as any one of an OTW, FW, or SMW catheter).

In a further alternative, if the physician initially prefers an SMW catheter, the inflatable seal in not inflated, thus allowing the corewire to move freely. The corewire may then be manipulated through the area of lesion, followed by proper positioning of the dilatation balloon over the corewire. Once the dilatation balloon is in the proper position, the inflatable seal is inflated to seal the distal tip of the catheter, and then inflation/deflation of the dilatation balloon is carried out as described above. Again, once the dilation is complete, the physician has all of the options noted above.

It should be further noted, that the catheter according to the present invention, may act as any of an OTW, FW, or SMW catheter at any time during the procedure, by simply inflating or deflating the inflatable seal. For example, the physician has the option of beginning the procedure with the inflatable seal inflated and the corewire locked in place and acting as an FW catheter, and then at a later stage of the procedure, deflating the inflatable seal thus releasing the corewire, so that the catheter acts as a SMW catheter. An infinite number of combinations and changes from one type of catheter to another may be carried out during a single angioplasty procedure, at the option of the physician. Therefore, the catheter according to the present invention is highly advantageous in providing all of the advantages of each type of catheter along with the versatility and ease of switching between the different types of catheters at any time during the angioplasty procedure.

The foregoing has been a description of certain preferred embodiments of the present invention, but is not intended to limit the invention in any way. Rather, many modifications, variations and changes in details may be made within the scope of the present invention.

What is claimed is:

1. A angioplasty catheter comprising:

    a catheter shaft having a proximal end and a distal end and having a main lumen and a secondary lumen extending therethrough from the proximal end to the distal end;

    a balloon extension having a proximal end and a distal end, the proximal end of said balloon extension being connected to the distal end of said catheter shaft, said balloon extension having an outer member and an inner member extending from the proximal end to the distal end of the balloon extension;

    wherein the proximal end of said outer member is continuous with said main lumen at its distal end and the distal end of said outer member comprises a distal tip of said catheter, and said outer member has a dilatation balloon formed in a portion of its length; and

    wherein said inner member is connected at its proximal end to the secondary lumen at its distal end, and the distal end of the inner member terminates in an inflatable seal disposed within said distal tip of said catheter.

2. A angioplasty catheter according to claim 1, wherein the diameter of said main lumen is 3 to 6 times the diameter of said secondary lumen.

3. A angioplasty catheter according to claim 2, wherein the outer diameter of said main lumen is approximately the same as the outer diameter of said outer member, and the diameter of said secondary lumen is approximately the same as the diameter of

the inner member.

4. A angioplasty catheter according to claim 1, wherein said catheter shaft and said balloon extension are formed from oriented polyethylene.

5. A angioplasty catheter according to claim 4, wherein said catheter shaft is heat bonded to said balloon extension.

6. A angioplasty catheter according to claim 4, wherein said catheter shaft is formed from high density polyethylene.

7. A angioplasty catheter according to claim 4, wherein said balloon extension is formed from linear low density polyethylene.

8. A angioplasty catheter according to claim 1, wherein said inner member is formed of oriented polyethylene.

9. A angioplasty catheter according to claim 8, wherein said inner member is formed from linear low density polyethylene.

10. A angioplasty catheter according to claim 8, wherein said inflatable seal is formed from said inner member by heating a portion of said inner member and applying pressure to inflate said inner member, thus forming a small balloon segment continuous with said inner member.

11. A angioplasty cathet r according to claim 10, wherein said inflatable seal is heat bonded within

said distal tip of said catheter.

12. A angioplasty catheter according to claim 1, wherein said inflatable seal is formed from an elastomeric material and bonded to said inner member.

13. A angioplasty catheter according to claim 1, further including a tapered corewire extending through the entire length of said main lumen and said outer member and extending out said distal tip of said catheter, the distal end of said tapered corewire terminating with a coil of radiopaque metal.

14. A angioplasty catheter according to claim 13, wherein said tapered corewire is made of stainless steel, or of an alloy of nickel and titanium (nitinol).

15. A angioplasty catheter according to claim 13, wherein said tapered corewire has a diameter of about .006" along a portion extending through said dilatation balloon.

16. A angioplasty catheter according to claim 13, wherein said tapered corewire is coated with Teflon, silicone, hydrogel, or other lubricous substance to reduce friction within said outer member.

17. A angioplasty catheter according to claim 1, wherein said catheter shaft and said balloon extension are bonded together at a position 5 to 35 cm proximal to the dilatation balloon.

18. A angioplasty catheter according to claim 1, further including first means for independently inflating

and deflating said inflatable seal and second means for independently inflating and deflating said dilatation balloon.

19. A angioplasty catheter according to claim 1, wherein the outer surface of said catheter is coated with a lubricous substance such as silicone or hydrogel, to reduce friction on the outer surface of said catheter.

20. A angioplasty catheter which may operate as any one of an over the wire catheter, fixed wire catheter, or semi-movable catheter, at the option of the operator; wherein said catheter may be infinitely switched from any one of said over the wire catheter, said fixed wire catheter, or said semi-movable catheter, to another one of said over the wire catheter, said fixed wire catheter, or said semi-movable catheter, at any time during operation of the catheter.

21. A method for purging an angioplasty catheter comprising the steps of: deflating a selectively inflatable seal located in the distal end of said catheter; allowing free efflux of air and fluid from an inflation lumen and dilatation balloon of said catheter; and inflating said inflatable seal to prevent leakage from said distal end of said catheter during use.

22. A angioplasty catheter comprising:

a coaxial two lumen catheter shaft, having an outer member extending therethrough from the proximal end to the distal end, and an inner member coaxially located within said outer member and also extending therethrough from the proximal end to the distal end;

wherein the distal end of said outer member comprises a distal tip of said catheter, and said outer member has a dilatation balloon formed along a portion of its length; and

wherein the distal end of the inner member terminates in a small inflatable seal disposed within said distal tip of said catheter.

23. A angioplasty catheter according to claim 22, wherein the diameter of said outer member is 3 to 6 times the diameter of said inner member.

24. A angioplasty catheter according to claim 22, wherein said outer member is formed of oriented polyethylene.

25. A angioplasty catheter according to claim 22, wherein said dilatation balloon is formed as a continuous part of said outer member by heating a portion of said outer member and applying pressure to inflate that portion.

26. A angioplasty catheter according to claim 22, wherein said dilatation balloon is formed as a balloon extension member, and said balloon extension member is heat bonded to said outer member.

27. A angioplasty catheter according to claim 24, wherein said outer member is formed from high density polyethylene.

28. A angioplasty catheter according to claim 27, wherein said dilatation balloon is formed from

linear low density polyethylene and is bonded to said outer member.

29. A angioplasty catheter according to claim 24, wherein said outer member is formed from linear low density polyethylene.

30. A angioplasty catheter according to claim 22, wherein said inner member is formed of oriented polyethylene.

31. A angioplasty catheter according to claim 30, wherein said inner member is formed from linear low density polyethylene.

32. A angioplasty catheter according to claim 30, wherein said inflatable seal is formed from said inner member by heating a portion of said inner member and applying pressure to inflate said inner member, thus forming a small balloon segment continuous with said inner member.

33. A angioplasty catheter according to claim 22, wherein said inflatable seal is heat bonded within said distal tip of said catheter.

34. A angioplasty catheter according to claim 22, wherein said inflatable seal is formed from an elastomeric material such as silicone, latex, or polyurethane and is bonded to the proximal end of said inner member and in a position distal to said distal tip of said catheter.

35. A angioplasty catheter according to claim 22, further including a tapered corewire extending

through the entire length of said main lumen and said outer member and extending out said distal tip of said catheter, the distal end of said tapered corewire terminating with a coil of radiopaque metal.

36. A angioplasty catheter according to claim 35, wherein said tapered corewire is made of stainless steel, or of an alloy of nickel and titanium (nitinol).

37. A angioplasty catheter according to claim 35, wherein said tapered corewire has a diameter of about .006" along a portion extending through said dilatation balloon.

38. A angioplasty catheter according to claim 35, wherein said tapered corewire is coated with Teflon, silicone, hydrogel, or other lubricous substance to reduce friction within said outer member.

39. A angioplasty catheter according to claim 22, further including first means for independently inflating and deflating said inflatable seal and second means for independently inflating and deflating said dilatation balloon.

40. A angioplasty catheter according to claim 22, wherein the outer surface of said catheter is coated with a lubricous substance such as silicone or hydrogel, to reduce friction on the outer surface of said catheter.

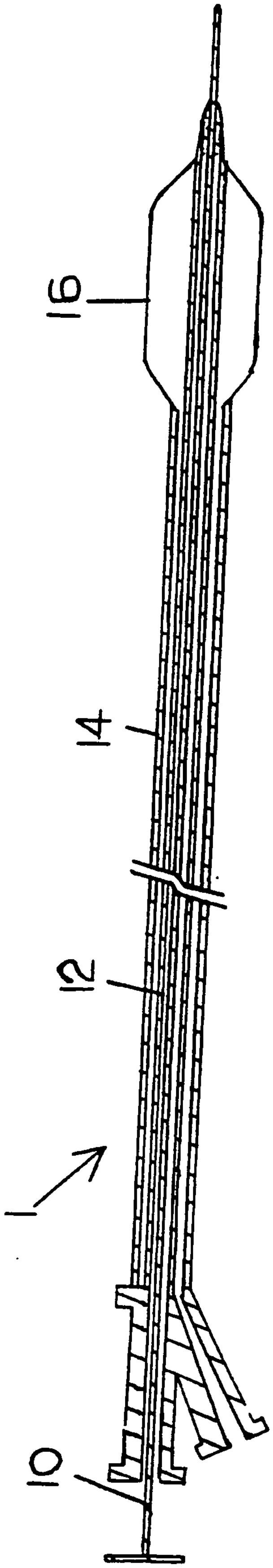


FIG. 1A

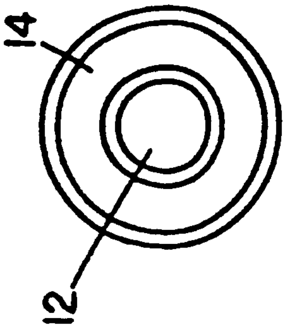


FIG. 1B

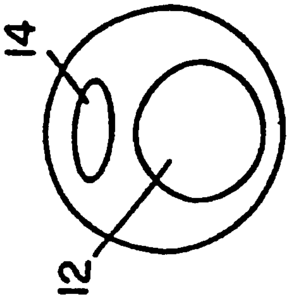


FIG. 1C

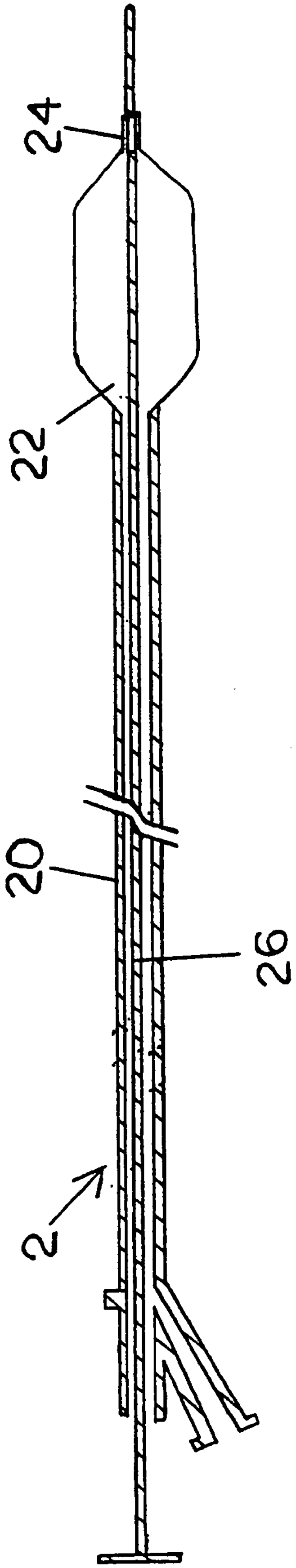


FIG. 2A

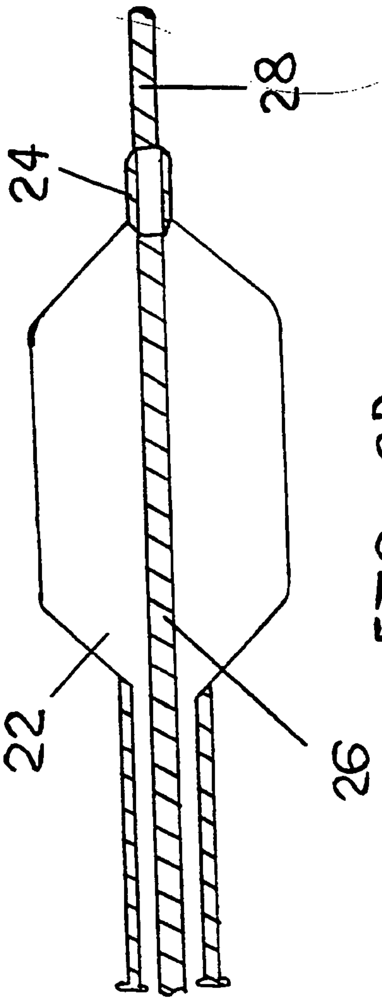


FIG. 2B

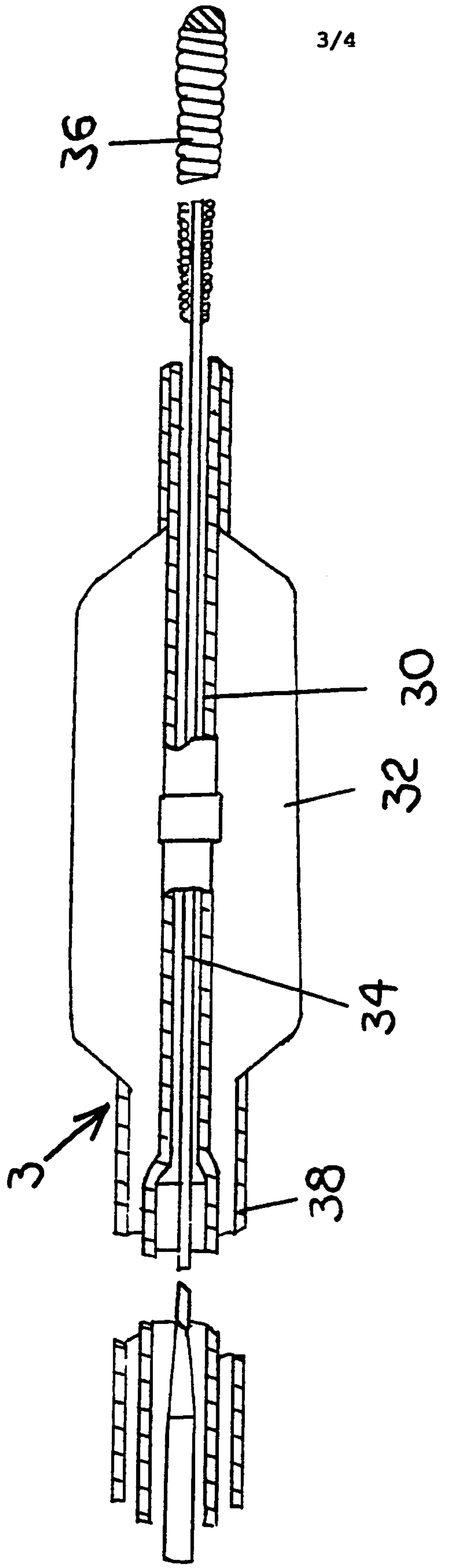


FIG. 3

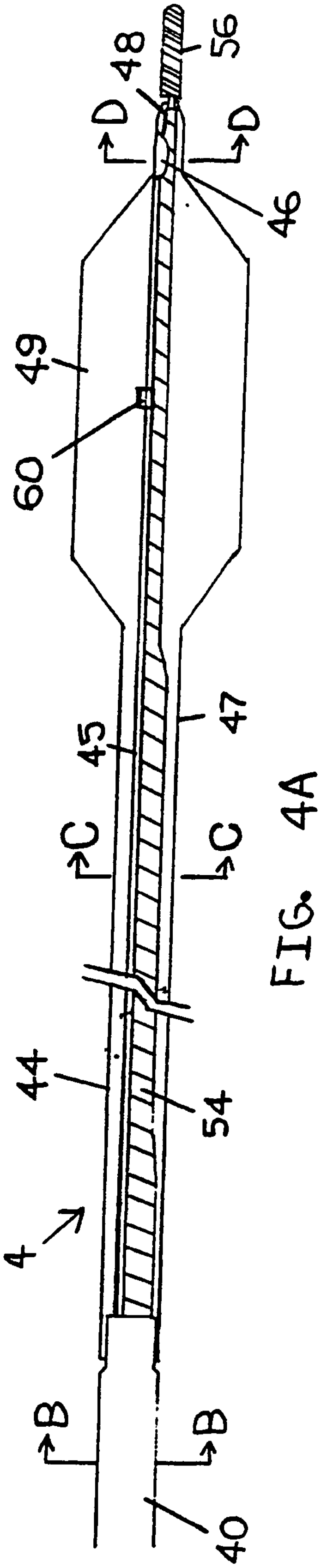


FIG. 4A

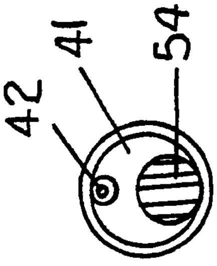


FIG. 4B

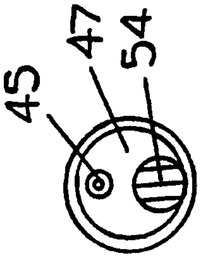


FIG. 4C

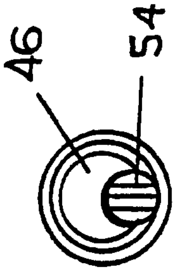


FIG. 4D

# INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/04753

**I. CLASSIFICATION OF SUBJECT MATTER** (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.5 A 61 M 29/02 A 61 M 25/01

**II. FIELDS SEARCHED**

Minimum Documentation Searched[7]

| Classification System | Classification Symbols |
|---|---|
| Int.Cl.5 | A 61 M |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

**III. DOCUMENTS CONSIDERED TO BE RELEVANT**[9]

| Category ° | Citation of Document, [11] with indication, where appropriate, of the relevant passages [12] | Relevant to Claim No.[13] |
|---|---|---|
| X | EP,A,0371486 (ADVANCED) 6 June 1990, see figures 2,3; column 3, line 54 - column 4, line 2 | 21 |
| A | | 1,22 |
| | --- | |
| A | DE,A,3528876 (SCHUBERT) 19 February 1987, see figure 3, item 13; column 5, lines 3-9 | 1,22 |
| | --- | |
| A | EP,A,0213750 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 11 March 1987, see abstract | 21 |
| | --- | |
| A | EP,A,0279959 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 31 August 1988 | |
| | ----- | |

° Special categories of cited documents : [10]

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

**IV. CERTIFICATION**

| | |
|---|---|
| Date of the Actual Completion of the International Search<br>31-10-1991 | Date of Mailing of this International Search Report<br>26. 11. 91 |
| International Searching Authority<br>EUROPEAN PATENT OFFICE | Signature of Authorized Officer<br>miss T. MORTENSEN |

Form PCT/ISA/210 (second sheet) (January 1985)

# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9104753
SA 49525

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 15/11/91
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|---|---|---|---|---|
| EP-A- 0371486 | 06-06-90 | US-A- | 4932959 | 12-06-90 |
| | | JP-A- | 2271874 | 06-11-90 |
| DE-A- 3528876 | 19-02-87 | None | | |
| EP-A- 0213750 | 11-03-87 | US-A- | 4638805 | 27-01-87 |
| | | AU-B- | 591919 | 21-12-89 |
| | | AU-A- | 6055186 | 05-02-87 |
| | | JP-A- | 62072371 | 02-04-87 |
| | | US-A- | 4692200 | 08-09-87 |
| EP-A- 0279959 | 31-08-88 | AU-A- | 1006788 | 07-07-88 |
| | | JP-A- | 63238859 | 04-10-88 |
| | | US-A- | 4976720 | 11-12-90 |

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82